Claim Rejection.

Item 9. To clarify: "25-<75 μg/L" was intended to read "25 to less than 75 μg/L." The examiner says the quoted phrase may have two meanings and is, therefore, uncertain. He misreads each of them: "25-<75 μg/L" means neither "25 to 75" nor "25 less than 75": the examiner ignores the "<" in his first interpretation and the "-" in his second choice. The examiner is correct to note that words are preferable to symbols in this phrase.

Item 11. U.S. Patent No. 6,309,672, referred to as Bae et al. in the Reference Citation and Bau et al. in the Office Action Summary, is seen by the examiner as a cause for obviousness rejection. The Bae patent describes an effective anti-cancer treatment of cancer patients associated with a treatment of arsenic hexoxide, a cyclic compound, at 160mg/day. Lower levels of exposure are ineffective, according to the Bae patent. So it would not be obvious that a much lower exposure range (specifically bound at one to three percent of the effective arsenic hexoxide dose, based on the examiner's calculation) of unspecified soluble arsenic compounds would be effective in preventing (not treating) cancers.

> If one to three percent of the arsenic hexoxide dose in soluble arsenic significantly reduced by more than two thirds the expected total cancer mortality in women in the Utah data set and significantly reduced by one quarter the expected heart disease mortality in men in the Utah data set, what would 100 percent (i.e., 2,500 μg/L) be expected to do? – Prevent 800 percent of the heart disease deaths and 2,200 percent of the cancer deaths. Quantitatively the soluble arsenic is so effective at one to three percent of the arsenic hexoxide dose that it is qualitatively different -- so it is not obvious: if soluble arsenic were to mimic the effect of dilute arsenic hexoxide, it should be virtually ineffective at one to three percent.
>
> Further, the specific regulatory claim made by another Federal Agency (EPA) is that the lower the arsenic level in drinking water, the lower the bladder cancer level, based on a high (600 to 934 μg/L range) to low (0 to 100 μg/L range) arsenic level extrapolation, citing multiple human studies generally but relying on the Taiwan data for specific risk calculations. There would be no expectation of a cancer (or any health) benefit being associated with "25 to less than 75 μg/L," compared a lower range. According to the EPA analysis, the greatest benefit in cancer reduction occurs in the absence of arsenic – so the applicant's claims can not be obvious based on the EPA analysis of human cancer data.

Correspondence and meeting records

Following the invitation of examiner James D. Anderson in Art Unit 1614, Applicant arranged for a discussion of points and issues raised in his Office Action Summary by telephone on May 19, 2006. The examiner, his newly named supervisor Ardin Marshel, and Gary Kayajanian participated in the conversation which lasted for about an hour. Pending claims 1-19 were discussed, in general and specific terms. The applicant agreed to specifically list and, where possible, provide copies of published and unpublished documents, including data sets, on which he developed claims 1-20. Examiner Anderson felt his access was hindered to papers and documents cited in the body of the patent document but not in "Notice of References Cited."

On May 22, 2006 spoke separately first with supervisor Marshel, then examiner Anderson about an interpretive issue: Marshel suggested a continuation of the three person teleconference be set up; Anderson thought no continuation was needed. The teleconference was not continued.

The examiner agreed to provide by US mail additional information, including forms, to assist the applicant in his response to the Office Action Summary. An incomplete package of material was promptly sent to the applicant; the excluded materials were mailed following a reminder.